REMARKS

Further prosecution of this application at the Examiner level is clearly pointless. With the issuance of the June 22, 2007 office action, the Patent Office has now issued a total of eight (8) office actions in this application dating from its filing date over five years ago on December 20, 2001. The applicant has been required to respond to each of those office actions and in so doing has filed a total of three requests for continued examination. This has resulted in a protracted prosecution, not to mention an expensive one.

The most recent office action is frankly insulting. It appears that no matter what amendment is made to the claims or viable argument is proffered, all seven million plus patents issued by the U.S. Patent and Trademark Office will be searched for some reference which, in isolation, discloses some structure which purportedly resembles the newly claimed feature. Failing to find that, the all encompassing argument that it would be obvious to modify the primary reference to arrive at the claimed subject matter will be made. Clearly neither of these grounds for rejection is appropriate, and applicants submit one last time that they should be withdrawn.[1] Should that not succeed, applicants are concurrently filing a notice of appeal to bring this matter to the attention of the Board of Patent Appeals and Interferences.

By way of background, the main reference upon which the Examiner has maintained his rejections throughout the five years of prosecution of this application is the Kenisburg patent, which as previously pointed out is not at all related to the field of endeavor of the pending subject matter, but rather is a device for measuring pressure proximate to the sphincter between the esophagus and the stomach. It discloses a multi-tubed embodiment

[1] "Determination of obviousness cannot be based on a hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention". *ATD Corp v Lydall, Inc*, 48 USPQ2d 1321 (Fed Cir 1998)

having a central sheath with a slideable tube within the sheath and first and second tubes on the outside laterally flanking the sheath. As shown in Fig 2, in cross section there is a large central circle with a concentric circle therein, and first and second circles 32 and 38 above and below those concentric circles. Each of those tubes are also of a different length and are necessarily so in that they need to reach to different depths within the human body, namely, to the esophagus above the sphincter, to the sphincter itself, and to the stomach below the sphincter.

When applicants first attempted to bring the facts that this patent is from a disparate art, and one of ordinary skill in the art of angioplasty would not look to the teachings of the gastrointestinal arts for guidance, to the attention of the Examiner he argued that the intended use of an apparatus is irrelevant with respect to patentability. If its structure can be used to perform the stated function, it would serve as prior art. This argument is in fact accurate. We could have, in turn, argued for the issuance of the method claims but those had previously been restricted out and applicants are delaying filing of that divisional until reaching positive resolution with this apparatus application.

The other option was to look for structural features in the pending disclosure which clearly differentiate over the gastrointestinal reflux apparatus of Kenisburg. Those structural limitations are many and one which was identified and added to the claims was the fact that the pending application is uniquely designed for introduction into small blood vessels, mainly arteries, where it is desired to perform an angioplasty and where the pending subject matter would be particularly advantageous for knowing the blood pressure on both sides of a stenosis. If the blood pressure differential between the two sides is of a sufficient level it would be deemed appropriate for an angioplasty to be performed, and if not, angioplasty can be avoided.

One structural feature which allows for the pending subject matter to perform this procedure is its small profile and circular configuration. Accordingly, in previous responses to office actions, this circular cross-sectional profile limitation has been added. As can be seen from Fig. 2 of Kenisburg, the circular configuration is clearly not specifically described and shown, but the Examiner has relied upon the nebulous wording of the Kenisburg specification stating that its structure "could be modified." Well, of course, most specifications include that hopefully broadening language, but the Examiner and the courts must apply some degree of reasonableness to the level to which a disclosed structure can be reasonably assumed to be considered by the inventor and fall within that potential modification range. Clearly, a structure which uses different tubes to measure different pressures along a linear length extending from the esophagus through the sphincter into the stomach, and which states that individual tubes are necessary for doing so, will not have a circular configuration.

Presumably realizing the weakness in his argument, the Examiner is now citing the Peacock, III patent application which by our count is the seventh individual reference which the Examiner has used to reject these claims throughout its five year prosecution. Once again however, the Examiner has embarked on a wide band search for a reference regardless of its individual field of endeavor which has at least one sentence or figure disclosing an individual claim element in isolation. Here, the Examiner sought to find a reference having a multi-tubed apparatus having an overall external configuration of a circle. In so doing, he is choosing to reject the angioplasty device of the pending application based on a device used in heart bypass surgery to allow for a portion of aorta to be isolated and operated upon while still allowing blood to be circulated through the body. How this is in any way related to measuring blood pressure on first and second sides of an occlusion to determine if

angioplasty is needed, is beyond the understanding of the applicant and his attorney. Clearly tubes within tubes have been known for decades. The Examiner could have cited any one of dozens of patents disclosing such a mechanical feature ranging from automotive manifolds to vacuum cleaners. If this were the only limitation to which the Examiner must abide, his argument would succeed, however, the patent laws are written in a different way. He must cite references which are within the same reasonable field of endeavor, which disclose each and every element of the pending claim, and which provide some motivation or suggestion to be combined or modified to arrive at the pending subject matter. As stated above, Kenisburg is related to a gastroesphogeal device which is multi-tubed and since the esophagus itself is a relatively large diameter lumen, a sleek design having tubes nested within others is not necessary. The newly cited Peacock, III reference is equally lacking. It is for use in open heart surgery. Introduction through small diameter lumens in the body is not sought in that the chest cavity itself is open during such a procedure, the ribs are spread, and the heart is directly accessed. Rather, Peacock, III is directed to a conduit for allowing the blood to circulate through the body while that open heart bypass surgery is being performed.

Getting back to the terms of the now pending claims, any *prima facie* case of obviousness which the Examiner relies on must include references which teach each and every element of the pending claim and provides some motivation and suggestion to be combined or modified. In addition, they must have some reasonable expectation of success. Applicants submit that none of these requirements of MPEP 2143 have been met by the Examiner. Neither of the references cited by the Examiner monitor blood pressure on two sides of a stenosis. In addition, there is no suggestion or motivation to combine the references to arrive at the pending disclosure. The first is a gastroesphogeal treatment device and the second is a heart bypass device. To argue that such disparate references somehow

would suggest the teaching of a circular low profile medical device for use in angioplasty, is overreaching at best, absurd at worst.

In light of the foregoing, applicants respectfully submit that the rejection of the Examiner should be withdrawn. Failing that, the enclosed notice of appeal is being filed concurrently herewith and an appeal brief will be filed in due time to bring the matter before the U.S. Patent and Trademark Office Board of Appeals.

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Respectfully submitted,

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